UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF CHEMICAL SAFETY AND POLLUTIION PREVENTION

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MEMORANDUM

August 12, 2011

SUBJECT: EFED Comments on the Completeness of Submitted Data Package for Cyantraniliprole by Syngenta and DuPont for Global Review

TO: Thomas Harris, Risk Manager
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Registration Division (7505P)

FROM: Meghan Radtke, Ph.D., Biologist 8/12/11
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THROUGH: Nancy Andrews, Ph.D., Branch Chief 8/12/11
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The Environmental Fate and Effects Division (EFED) completed its review of Syngenta and DuPont's data package for cyantraniliprole for global review. The environmental fate data package is complete except for an independent laboratory validation (ILV) in air (**Table 1**). In addition, the initial screen of the environmental effects data package shows it to be complete (**Table 2**). After the secondary review of the submitted data, EFED will confirm whether submitted data for cyantraniliprole are sufficient for completing an ecological risk assessment. If the results of one or more reviews indicate that further data are required or other issues are identified, EFED will provide a letter of evaluation deficiency upon completion of the reviews.

Table 1. New Chemical Screening Summary – Cyantraniliprole (DX-HGW86) – Environmental Fate

Guideline	MRID	Study Title	Guideline Issues	Reviewable (Yes/No)	Comments
835.2120 (161-1)	48119905	Hydrolysis	No issues affecting the acceptability of the study were identified.	Yes	pH 4, 7 and 9 buffers incubated at 15, 25, and 35°C. Most stable at pH 4.
835.2240 (161-2)	48119906 48122540	Photodegradation in Water	No issues affecting the acceptability of the study were identified.	Yes	Conducted in pH 4 buffer and sterilized natural water; photodegrades in <1 day in both. 48122540 is a supplement concerning transformation product identification.
835.2410 (161-3)	48120046	Photodegradation on Soil	No issues affecting the acceptability of the study were identified.	Yes	Dry soil with continuous irradiation. No significant photodegradation.
	48120082			Yes	Wet soil and a 12-hour light/12-hour dark cycle. Significant photodegradation.
835.2370 (161-4)	---	Photodegradation in Air	---	---	---
835.4100 (162-1)	48120043	Aerobic Soil Metabolism	Incubation temperature was ± 3°C.	Yes	Two soils, one from US and one from France. 358 days of incubation. Includes Koc analysis of desorption of residues from aged soil.

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Guideline	MRID	Study Title	Guideline Issues	Reviewable (Yes/No)	Comments	
	48120045		In two of three soils at termination (120 days), undegraded parent ranged from 27-46% of applied.	Yes	Three soils, one from US, one from Germany, one from Spain. 120 days of incubation. Incubation temperatures of 10 and 20°C. DT50 16-90 days. Includes Koc analysis of desorption of residues from aged soil.	
	48120060		At termination (120 days), undegraded parent ranged from 29-59% of applied.	Yes	Degradate IN-J9Z38, cyano label. Five soils, two US and one each from France, Germany, and Spain. 120 days of incubation. DT50 77-200 days.	Conduct of the studies appears to be identical except for label position. The reason for the difference in DT50s could not be determined in the screen.
	48120061		No issues affecting the acceptability of the study were identified.	Yes	Degradate IN-J9Z38, pyrazole label. Five soils, two US and one each from France, Germany, and Spain. 120 days of incubation. DT50 3-12 days.	

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Guideline	MRID	Study Title	Guideline Issues	Reviewable (Yes/No)	Comments
	48120062		At termination (120 days), undegraded parent ranged from 38-69% of applied.	Yes	Degradate IN-JSE76. Five soils, two US and one each from France, Germany, and Spain.. 120 days of incubation. DT50 85-840 days.
	48120063		At termination (120 days), undegraded parent ranged from 45-90% of applied.	Yes	Degradate IN-K5A78. Five soils, two US and one each from France, Germany, and Spain. 120 days of incubation. DT50 94-1,055 days.
	48120064		In three soils at termination (120 days), undegraded parent ranged from 41-60% of applied.	Yes	Degradate IN-K5A77. Five soils, two US and one each from France, Germany, and Spain. 120 days of incubation. DT50 24-340 days.
	48120070		In two soils at termination (120 days), undegraded parent ranged from 46-55% of applied.	Yes	Degradate IN-K5A79. Five soils, two US and one each from France, Germany, and Spain. 120 days of incubation. DT50 19-131 days.

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Guideline	MRID	Study Title	Guideline Issues	Reviewable (Yes/No)	Comments
	48120074		At termination (121 days), undegraded parent ranged from 74-92% of applied.	Yes	Degradate IN-PLT97. Five soils, two US and one each from France, Germany, and Spain. 121 days of incubation. DT50 429-1,744 days. Includes Koc analysis of desorption of residues from aged soil.
	48120083		At termination (120 days), undegraded parent ranged from 38-67% of applied.	Yes	Degradate IN-QKV54. Five soils, two US and one each from France, Germany, and Spain. 120 days of incubation. DT50 74-215 days. An HPLC peak containing >10% of applied could not be adequately characterized despite analysis; this peak contained one or more very polar compounds.
	48120087		Two transformation products were not identified. In two soils at termination (120 days), undegraded parent ranged from 40-57% of applied.	Yes	Degradate IN-RNU71. Five soils, two US and one each from France, Germany, and Spain. 120 days of incubation. DT50 42-175 days.

Table 1. New Chemical Screening Summary – Cyantraniliprole (DX-HGW86) – Environmental Fate

Guideline	MRID	Study Title	Guideline Issues	Reviewable (Yes/No)	Comments
835.4200 (162-2)	48120047	Anaerobic Soil Metabolism	No issues affecting the acceptability of the study were identified.	Yes	One soil from France. 10 Days aerobic followed by 120 days anaerobic.
845.4300 (162-4)	48120049	Aerobic Aquatic Metabolism	No issues affecting the acceptability of the study were identified.	Yes	Water/sediment from one site in UK and one in France. 100 days of incubation. Differentiates between rate of dissipation and rate of degradation in the water phase.
	48120079		Not intended to fulfill guidelines	Yes	Water/sediment from two sites in UK. Three w/s experiments, one with samples exposed to sunlight, one dark control, and one with samples in an open container, plus a buffer-only control. 14 days of incubation
835.4400 (162-3)	48120081	Anaerobic Aquatic Metabolism	No issues affecting the acceptability of the study were identified.	Yes	Water/sediment from one site in UK. 100 days of incubation.
	48120071		No issues affecting the acceptability of the study were identified.	Yes	Water/sediment from one site in UK. 353 days of incubation.

Table 1. New Chemical Screening Summary – Cyantraniliprole (DX-HGW86) – Environmental Fate

Guideline	MRID	Study Title	Guideline Issues	Reviewable (Yes/No)	Comments
835.1230 (163-1)	48120065	Mobility - Adsorption/Desorption	No issues affecting the acceptability of the studies were identified.	Yes	IN-J9Z38. 5 soils (2 US, 3 European). 5 concentrations. Desorption (2 steps) on highest concentration only. Soil:solution ratio (w:v) of 1:21.
	48120066			Yes	IN-JCZ38. 5 soils (2 US, 3 European). 5 concentrations. Desorption (2 steps) on highest concentration only. Soil:solution ratio (w:v) of 1:4
	48120067			Yes	IN-JSE76. 5 soils (2 US, 3 European). 5 concentrations. Desorption (2 steps) on highest concentration only. Soil:solution ratio (w:v) of 1:1.
	48120068			Yes	IN-K5A78. 5 soils (2 US, 3 European). 5 concentrations. Desorption (2 steps) on highest concentration only. Soil:solution ratio (w:v) of 1:10 for US soils and 1:4 for European soils.

Table 1. New Chemical Screening Summary – Cyantraniliprole (DX-HGW86) – Environmental Fate

Guideline	MRID	Study Title	Guideline Issues	Reviewable (Yes/No)	Comments
	48120069			Yes	IN-K5A77. 5 soils (2 US, 3 European). 5 concentrations. Desorption (2 steps) on highest concentration only. Soil:solution ratio (w:v) of 1:21.
	48120072			Yes	IN-K5A79. 5 soils (2 US, 3 European). 5 concentrations. Desorption (2 steps) on highest concentration only. Soil:solution ratio (w:v) of 1:4
	48120073			Yes	DX-HGW86 (Cyantraniliprole). 5 soils (2 US, 3 European). 5 concentrations. Desorption (2 steps) on highest concentration only. Soil:solution ratio (w:v) of 1:4
	48120075			Yes	IN-PLT97. 5 soils (2 US, 3 European). 5 concentrations. Desorption (2 steps) on highest concentration only. Soil:solution ratio (w:v) of 1:10.

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Guideline	MRID	Study Title	Guideline Issues	Reviewable (Yes/No)	Comments
	48120086			Yes	IN-QKV54. 5 soils (2 US, 3 European). 5 concentrations. Desorption (2 steps) on highest concentration only. Soil:solution ratio (w:v) of 1:20.
	48120088		Adsorption/desorption was tested at only three concentrations., with highest concentration 15x greater than lowest.	Yes	IN-RNU71. 5 soils (2 US, 3 European). 3 concentrations. Desorption (2 steps) on highest concentration only. Soil:solution ratio (w:v) of 1:4
835.1240 (163-1)	---	Mobility - Column Leaching	---	---	---
835.1410 (163-2)	---	Laboratory Volatility	---	---	---
835.8100 (163-3)	---	Field Volatility	---	---	---
835.6100	48120050	Terrestrial Field Dissipation	No issues affecting the acceptability of the studies	Yes	One bareground site in Spain. 450 g/ha. 540 days.

Table 1. New Chemical Screening Summary – Cyantraniliprole (DX-HGW86) – Environmental Fate

Guideline	MRID	Study Title	Guideline Issues	Reviewable (Yes/No)	Comments
(164-1)	48120051		were identified.	Yes	One bareground site in France. 450 g/ha. 541 days.
	48120052		The soils were initially analyzed only for parent and seven transformation products. Several of the soils were later analyzed for three photoproducts; the results are presented in separate MRIDs.	Yes	One bareground site in Germany. 300 g/ha. 538 days.
	48120053			Yes	One bareground site in New York. 300 g/ha. 514 days (17 months).
	48120054			Yes	One bareground (450 g/ha) and one cropped (225 g/ha x 2) site in Washington state. 534 days.
	48120055		Freezer storage stability data were provided in separate MRIDs.	Yes	One bareground (450 g/ha) and one cropped (225 g/ha x 2) site in California. 539 days.
	48120056			Yes	One bareground (450 g/ha) and one cropped (225 g/ha x 2) site in Missouri. 541 days.
	48120057			Yes	One bareground site in Manitoba, Canada. 300 g/ha. 502 days.

Table 1. New Chemical Screening Summary – Cyantraniliprole (DX-HGW86) – Environmental Fate

Guideline	MRID	Study Title	Guideline Issues	Reviewable (Yes/No)	Comments
	48120058			Yes	One bareground site in Texas. 300 g/ha. 539 days.
	48120059			Yes	One bareground site in Italy. 300 g/ha. 541 days.
835.6200 (164-2)	---	Aquatic Sediment Dissipation	---	---	---
835.6300 (164-3)	---	Forestry Dissipation	---	---	---
835.1730 (165-4)		Fish Accumulation	---	---	---
835.1950 (165-5)	---	Accumulation in Aquatic Non-target Organisms	---	---	---
166-1	---	Groundwater	---	---	---

Table 1. New Chemical Screening Summary – Cyantraniliprole (DX-HGW86) – Environmental Fate

Guideline	MRID	Study Title	Guideline Issues	Reviewable (Yes/No)	Comments
N/A	48120077	*Other Special Studies*	No issues affecting the acceptability of the study were identified.	Yes	OECB 301B, CO_2 Evolution Test
	48120131		No issues affecting the acceptability of the study were identified.	Yes	OECB 209, Activated sludge, 5 concentrations.
	48120076		No issues affecting the acceptability of the study were identified.	Yes	Storage stability of parent and degradates using California and French soils.
	48120080		No issues affecting the acceptability of the study were identified.	Yes	Analysis/comparison of laboratory and field study conditions and results
	48120084		No issues affecting the acceptability of the study were identified.	Yes	Reanalysis of TFD soils for photoproducts (IN-NXX70, IN-QKV54, IN-RNU71). Canada, New York, Texas soils.

Table 1. New Chemical Screening Summary – Cyantraniliprole (DX-HGW86) – Environmental Fate

Guideline	MRID	Study Title	Guideline Issues	Reviewable (Yes/No)	Comments
	48120085		No issues affecting the acceptability of the study were identified.	Yes	Reanalysis of TFD soils for photoproducts (IN-NXX70, IN-QKV54, IN-RNU71). Germany, Italy soils.
	48122591		No issues affecting the acceptability of the study were identified.	Yes	Storage stability of parent and photodegradates, North American soils.
	48208449		No issues affecting the acceptability of the study were identified.	Yes	Summary of results of TFD studies
	48119921 48122528		No issues affecting the acceptability of the study were identified.	Yes	48119921 is the ECM for parent and products in soil, with 48122528 the ILV of soil ECM

Table 1. New Chemical Screening Summary – Cyantraniliprole (DX-HGW86) – Environmental Fate

Guideline	MRID	Study Title	Guideline Issues	Reviewable (Yes/No)	Comments
	48122524		No issues affecting the acceptability of the study were identified.	Yes	Comparison of extraction efficiencies of methods used for residue analyses versus metabolism analyses. Extraction solvents were the same; the methods differed in number of extractions and extraction intervals. Residues from aged soils were extracted.
	48122527 48122535		No issues affecting the acceptability of the study were identified.	Yes	48119927 is the ECM for parent and products in water, with 48122535 the ILV of water ECM.
	48119937 48119927		No ILV for parent. Data presented as ILV for transformation products is not a valid ILV because it was conducted by the same laboratory as the ECM	Yes	48119937 is the ECM for parent and photoproducts in soil. 48122527 is presented as the ILV for photoproducts (no parent) but is not a true ILV because both studies conducted by same laboratory.
	48119930		No ILV provided	Yes	ECM for parent in air

Table 2. New Chemical Screening Summary – Cyantraniliprole – Environmental Effects

Guideline	MRID	Study Title	Issues	Reviewable (Yes/No)
850.2100	48120153	Avian Oral Toxicity (non-passerine) - Northern bobwhite	No issues affecting the acceptability of the study were identified.	Yes
	48120171	Avian Oral Toxicity (passerine) - Zebra finch		
850.2200	48120128	Avian Dietary Toxicity - Northern bobwhite	No issues affecting the acceptability of the study were identified.	Yes
	48120127	Avian Dietary Toxicity - Mallard		
850.2300	48120115	Avian Reproduction - Mallard	No issues affecting the acceptability of the study were identified.	Yes
	48120116	Avian Reproduction - Northern bobwhite		
850.1010	48120114	Acute Toxicity Freshwater Invertebrates - Water flea	No issues affecting the acceptability of the study were identified.	Yes
	48122521			
	48120103	Acute Toxicity Freshwater Invertebrates - Stonefly	< 2 hour acclimation period for test species. Precipitate may not have been centrifuged from the 18 mg /L test solution before analysis.	Yes
	48120099	Acute Toxicity Freshwater Invertebrates - Mayfly	2 hour acclimation period for test species.	Yes
	48120117	Acute Toxicity Freshwater Invertebrates - Caddisfly	One hour acclimation period for test species	Yes
	48120111	Acute Toxicity Freshwater Invertebrates - Crayfish	Not all samples with observed precipitate were centrifuged before analysis.	Yes
	48120102	Acute Toxicity Freshwater Invertebrates - Amphipod	30% variation between the mean measured initial and final concentration in one test chamber.	Yes
	48120098		Mixed age organisms used. Concentration varied more than 20% in two of the test chambers from the mean measured initial and final concentrations in two test chambers.	Yes

	48120094	Acute Toxicity Freshwater Invertebrates - Midge	There was 24% variation between the initial and final mean measured samples taken from one test chamber.	Yes
	48120101	Acute Toxicity Freshwater Invertebrates - Oligochaete	Precipitate may not have been centrifuged from highest test solution before analysis. Initial measured concentrations were 22 – 27% higher than the final measurement.	Yes
850.1025	48120095	Acute Toxicity Estuarine and Marine Organisms - Oyster	No issues affecting the acceptability of the study were identified.	Yes
850.1035	48120096	Acute Toxicity Estuarine and Marine Organisms - Mysid	No issues affecting the acceptability of the study were identified.	Yes
850.1075	48120108	Freshwater Fish Toxicity - Rainbow trout	25.5 hour fasting period. Precipitate may not have been centrifuged from highest test solution before analysis. No concentration at 48 hours.	Yes
	48120106	Freshwater Fish Toxicity - Channel catfish	Precipitate may not have been centrifuged from 7 mg/L test solution before analysis. Pump malfunction that decreased measured concentrations of ai down to 44 – 55% of the nominal.	Yes
	48120104	Freshwater Fish Toxicity - Bluegill sunfish	26 hour fasting period. Precipitate may not have been centrifuged from test solutions before analysis.	Yes
	48120105	Acute Toxicity Estuarine and Marine Organisms - Sheepshead minnow	Precipitate may not have been centrifuged from test solutions before analysis. 25% difference between the mean measured sample on Day 0 and Day 2 in the 12 mg ai/L treatment group.	Yes
850.1300	48120089	Aquatic Invertebrate Life Cycle (Freshwater) -	Test duration was only 7 days. Test concentrations	Yes

		Water flea	were not measured. No information was provided about the health of the brood colony prior to the test.	
	48120091		Some renewal concentrations measured 20-30% higher in concentration than the old solution.	Yes
	48120133		The solvent control group produced 22% fewer young than the negative control.	Yes
	48120134		The solvent control group produced 24% more young than the negative control.	Yes
850.1350	48120097	Aquatic Invertebrate Life Cycle (Saltwater) - Mysid	No issues affecting the acceptability of the study were identified.	Yes
850.1400	48120109	Fish Early Life Stage (Freshwater) - Rainbow trout	No issues affecting the acceptability of the study were identified.	Yes
	48120110	Fish Early Life Stage (Estuarine/Marine) - Sheepshead minnow		
850.3020	48120090	Honeybee Acute Contact Toxicity - Honeybee	Missing negative control (i.e., control without wetting agent).	Yes
850.3030	48120132	Honeybee Toxicity of Residues on Foliage - Honeybee	No issues affecting the acceptability of the study were identified.	Yes
850.3040	48122564	Field Testing for Pollinators - Honeybee	All colonies exhibited reproductive stress.	Yes
	48122550			
	48122549			
	48122548			
	48120138			
	48120112		No issues affecting the acceptability of the study were identified.	Yes
	48122547			
	48122546			
	48122545			
	48208408			
	48120135			
	48120136			
	48122552		Bees may have had access to flowering weeds and	Yes

			ornamentals. Some hives were treated with pesticides to combat a *Varroa* mite infestation.	
	48122551		Cyantraniliprole residues were found in the control pollen samples. Bees may have had access to flowering weeds and ornamentals.	Yes
	48122557		Delay in the second application of cyantraniliprole decreased exposure intensity. Some hives had access to flowering dandelions.	Yes
	48122553		6 colonies died during the study. Delay in second application for Treatment 2. Bees may have had access to flowering weeds and ornamentals.	Yes
	48122558		The T1 and T2 fields were not far enough apart (< 2km). All bees may have had access to flowering weeds and ornamentals.	Yes
850.4100	48122575	Seedling Emergence	Adjuvant effect on corn (Tier 1 test). No adjuvant control included for Tier 2 test.	Yes
	48120174		No issues affecting the acceptability of the study were identified.	Yes
850.4150	48120186	Vegetative Vigor	No adjuvant control was included in the Tier 2 test.	Yes
	48120173		No issues affecting the acceptability of the study were identified.	Yes
850.4400	48122541	Aquatic Plant Growth – Blue-green algae	Precipitate may not have been centrifuged from test solutions before analysis.	Yes
	48120107	Aquatic Plant Growth - Green algae	Test duration was 72 hours instead of 96 hours. Precipitate may not have been centrifuged from	Yes

			nominal 11 and 22 mg ai/L test solutions before analysis. Sonification to break up cells is not permitted for this species. Compound degraded up to nearly 50% during the study.	
	48120157	Aquatic Plant Growth - Freshwater diatom	Precipitate may not have been centrifuged from Day 0 nominal 11 and 22 mg ai/L test solutions before analysis. Almost 50% variation between the measured concentration on Day 0 and Day 4 in some of the samples.	Yes
	48122542	Aquatic Plant Growth - Marine diatom	Precipitate may not have been centrifuged from Day 0 nominal 22 mg ai/L test solution before analysis. 50 - 74% variation between the measured concentration on Day 0 and Day 4 in several of the samples.	Yes
850.5400	48122543	Aquatic Plant Growth - Duckweed	Precipitate may not have been centrifuged from Day 0 nominal 22 mg ai/L test solution before analysis. Degradation by more than 70% between renewals in some test chambers.	Yes
N/A	48120093 48120092	Whole Sediment: Chronic Invertebrates Freshwater - Midge	No issues affecting the acceptability of the study were identified.	Yes